K082261

NOV - 6 2008

510(k) Summary
510(k) Number K08

dXRAD Solutions Ltd.
1000, 888 3rd Street SW
Calgary, AB, Canada T2P 5C5
Phone + 1 403 471 4409
Fax + 1 403 287 0704
Date Prepared: August 1, 2008
Contact: Darryl Stein, President

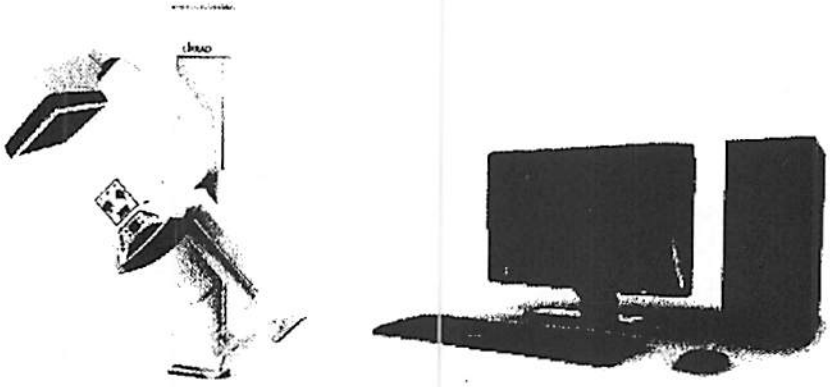
1. **Identification of the Device:**
   Proprietary-Trade Name: DX800 & DX808 Digital Diagnostic Radiographic Systems
   Classification Name: Stationary x-ray system, Product Codes KPR and MQB
   Common/Usual Name: Stationary Digital Diagnostic X-Ray

2. **Equivalent legally marketed device:** The Sedecal Optima URS, K012546 and the Vieworks Model QXR-9 (K073056) OR the Vieworks QXR-16 (K080553) and other comparable combination digital and x-ray systems, for example the Vidar Vision 3000 and Vidar Vision 4000 (K071193).

3. **Indications for Use** (intended use) These radiographic systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. **Description of the Device:** This digital diagnostic x-ray system consists of a tubehead/collimator assembly mounted on a U-Arm suspension along with a generator, generator control, and a mobile patient table. Power ratings for the available generators are in the rage of 32 kw to 80 kW. 64 kw is the standard size. Exposure voltage range varies from 40 – 125 KV or 40 – 150 kV with current of 300 - 100 mA. Exposure time is 1 ms – 10s. The system is provided with a digital imaging detector, either the QXR16 or the QXR9 CCD Image Detector and Acquisition Workstation. This device represents the interconnection of two already cleared devices: The X-ray system and the digital detector system.

5. **Safety and Effectiveness,** comparison to predicate device. The results of bench and test laboratory indicates that the new device is as safe and effective as the predicate devices.



6. Substantial Equivalence Chart

Characteristic	Vidar Vision 3000 and Vidar Vision 4000 (K071193).	DX800 & DX808 Digital Diagnostic Radiographic Systems
Intended Use:	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	SAME
Configuration	Column mount	SAME
Performance Standard	21 CFR 1020.30	SAME
Detectors	3056 x 3056 (9 megapixels) or 4096 x 4096 (16 megapixels)	SAME
Generator	High frequency made by Sedecal	Uses same generator made by Sedecal
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

7. Conclusion

After analyzing bench and external laboratory testing to applicable standards, it is the conclusion of dxRAD that the DX800 & DX808 Digital Diagnostic Radiographic Systems are as safe and effective as the predicate devices, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

dXRAD Solutions Ltd.
% Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

AUG - 9 2013

Re: K082261
Trade/Device Name: DX800 & DX808 Digital Diagnostic Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: August 4, 2008
Received: September 23, 2008

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of November 6, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K082261

Indications for Use

Device Name: DX800 & DX808 Digital Diagnostic Radiographic Systems

Indications For Use:
These Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082261